c.) Remarks

The claims have been amended to better recite the present invention with specifity required by statute. The subject matter of the amendment ("0.7ton/cm^2") may be found in the specification as filed, *inter alia*, at Experiment 1 (see Table 2 at specification page 50) and by converting the unit of 500kg/punch in experiments 3 and 4 into ton/ cm^2 ("1.3ton/cm^2"). Accordingly, no new matter has been added.

In the January 19, 2006 Advisory Action, the Examiner stated the application was not in condition for allowance because

- the feature that granules are not destroyed is not recited in the claims
- the prior art does not have to show each and every property claimed
- the feature that lubricant is applied only on punch and die surfaces is not recited in the claims
- the features of tablet hardness and tabletting pressure are not recited in the claims
- the sustained release profile of the present invention is not recited in the claims

In that regard, Applicant respectfully wish to point out it is simply not necessary to recite unexpected advantages in the claims (see *In re Chu,* 66 F.3rd 292 (Fed. Cir. 1995)). Additionally, the prior art need not show every property claimed only when the rejection is for anticipation, not for obviousness (*In re Best*, 562 F.2d 1252 (CCPA 1977)). Nonetheless, in conformity with the Examiner's kind suggestions, the claims have been amended above to recite tabletting pressure and that lubricant is applied only on the punch and die surfaces.

As the Examiner will appreciate, Applicants have discovered tabletting processes that maintain a function of a compressed tablet in which granule containing an active substance with a coating film is not destroyed, or maintain a function of a compressed tablet in which granule containing an active substance in a base matrix is not destroyed. These processes are generally characterized in that a lubricant is provided on the surface of tablet by lubricating only the punches and dies of a tabletting machine and comprising the tablet at tabletting pressure of 0.7 to 1.3 ton/cm^2. By this process, granules including a coated active substance or an active substance being in a base matrix are functionally maintained, even while providing a tablet with sufficient hardness.

As seen in experiments 1, 3 and 4, a tablet with sufficient hardness can be obtained at tabletting pressure of 0.7, 1.3, 2.6 and 3.9 ton/cm^2, so that it is clear that a tablet with sufficient hardness can be obtained at least at tabletting pressure of 0.7 - 1.3 ton/cm^2. Further, according to experiments 3 and 4, the granule is not destroyed at tabletting pressure of 1.3 ton/cm^2, so that it is clear that the granule is not destroyed at lower tabletting pressure namely 0.7 - 1.3 ton/cm^2.

Applicants wish to explain below how the data shown in the specification compares the result of the present invention and the cited references.

Tables I and II show the composition of the tablets produced in the experiment 3 and the experiment 4 (see from specification page 62, line 5 to page 64, line 19). It is clear that the amount of lubricant applied on the surface of the tablet of the experiment 4 is 0. 03% by weight as described in the experiment 1 of the embodiment of the invention 1 (see from page 46, line 17 to page 47, line 7).

Table I

	experiment 3	comparison 4
granule of reference 1	1000g	1000g
lactose	700g	700g
crystalline cellulose	300g	280g
magnesium stearate (to be mixed with molding material)	0g	20g (1.0% by weight)
magnesium stearate (to be provided on tablet's surface)	0.07 % by weight	0 % by weight

Table II

	embodiment 4	comparison 5
granule of reference 2	500g	1000g
lactose	350g	700g
crystalline cellulose	150g	280g
magnesium stearate (to be mixed with molding material)	0g	20g (1.0% by weight)
magnesium stearate (to be provided on tablet's surface)	0.03 % by weight	0 % by weight

Table III shows the tabletting pressure and the hardness of obtained tablet (table III is rewritten from specification table 3 with tabletting pressure recalculated into units of ton/cm^2). As shown in Table III, the tablet of the present invention in experiments 3 and 4 has superior hardness even when it is tabletted at low pressure. In contrast, the tablet of comparisons 4 and 5 in which a lubricant of 1% by weight is added to a molding material containing the theophylline granule or a microcapsule formed with enteric coating does not have enough hardness when tabletted at a low tabletting pressure.

Table III

tabletting pressure (ton/cm^2)		tablet hardness		
	experiment 3	comparison 4	experiment 4	comparison 5
1.3	5.0 (tablet of experiment 5)	2.0	5.5 (tablet of experiment 6)	2.0
2.6	10.0	4.5 (tablet of comparison 7)	11.0	5.0 (tablet of comparison 8)
3.9	14.0	9.0	15.0	9.5

Tables IV and V show the result of elution test using tablets with hardness of 4.5 - 5.5. Comparisons are conducted between the tablet of experiment 5 and the tablet of comparison 7, and between the tablet of experiment 6 and the tablet of comparison 8 shown from Table III.

Table IV

elution time (hr)	solution	experiment 5	comparison 7	reference 1
0	Japanese Pharmacopoeia first solution	0	0	0
0.25		5	15	5
0.50		12	40	10
0.75		15	65	15
1.00		22	80	20
1.50		30	95	30
2.00		41	100	40
(2.00)	Japanese Pharmacopoeia second solution	41	100	40
2.50		51	100	50
3.00		61	100	60
4.00		82	100	80
5.00		100	100	100

Table V

elution time (hr)	solution	experiment 6	comparison 8	reference 2
0	Japanese Pharmacopoeia first solution	0	0	0
0.25		0	30	0
0.50		0	70	0
0.75		0	95	0
1.00		0	100	0
1.50		0	100	0
2.00		2	100	1
(2.00)	Japanese Pharmacopoeia second solution	2	100	1
2.50		55	100	60
3.00		100	100	100
4.00		100	100	100
5.00		100	100	100

Table IV compares results of the sustained release of the tablet in the experiment 5 and the tablet in the comparison 7. Granules of the prior art are shown for comparison. As seen in table IV, the tablet of the present invention shows the same sustained release as the granule in the reference 1. However in comparison 7, because the release time of active substance is fast, it is understood the granules are destroyed. Accordingly, it is seen that the tablet of the experiment 5 is compressed without destroying the contained granule but with appropriate hardness.

Table V compares the sustained release of the tablet in the experiment 6 and the tablet in the comparison 8 The granule in the reference 2 is shown as a comparison object. In table V, the tablet of the present invention shows the same enteric ability as the granule in the reference 2, accordingly it is understood the contained granules are not destroyed. However, in comparison 8, since the active substance is released in the first solution of the Japanese Pharmacopoeia, it is understood again that the granules are

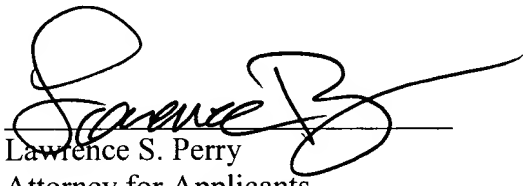
destroyed. Therefore, it is understood that the tablet of the experiment 6 is compressed without destroying the contained granule but has appropriate hardness.

Entry hereof is earnestly solicited.

Claims 42-53, 63-70 and 72-79 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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